

UNITED STATES DISTRICT COURT
DISTRICT OF PUERTO RICO

HELEN RIVERA ADAMS, et al.,

Plaintiffs,

v.

WYETH,

Defendant.

Civil No. 03-1713 (JAF)

ORDER

Defendant Wyeth has brought a “Motion for Summary Judgment,” a “Motion to Preclude Any Expert Testimony that Prempro Use Increases Breast Cancer Risk When Taken for Only Nineteen Months,” and various motions to exclude the individual testimony of certain plaintiffs’ expert witnesses. (Docket Nos. 49; 50; 52; 53; 54; 57; 136; 139; 143; 149; 151.) Plaintiffs oppose. (Docket Nos. 120; 123; 124; 125; 129; 130.) Oral arguments regarding Defendant’s challenge to admissibility of testimony related to the short term use of Prempro were heard on November 29, 2010. We address Defendant’s Motion for Summary Judgment in a companion order, and dispose of the threshold Daubert issues below.

I.

Daubert Standard

Rule 702 of the Federal Rules of Evidence governs the admission of expert testimony, and “requires that expert testimony be (1) based upon sufficient facts or data, (2) the product of reliable principles and methods, and (3) that the witness apply the principles and methods reliably to the facts of the case.” Pages-Ramirez v. Ramirez-Gonzalez, 605 F.3d 109, 113 (1st

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1 Cir. 2010) (citing Fed. R. Evid. 702). To be admissible, expert testimony must consist of
2 “(1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact
3 in issue.” Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592 (1993). In other words, the trial
4 judge must determine whether an “expert’s testimony ‘both [(1)] rests on a reliable foundation
5 and [(2)] is relevant to the task at hand.’” United States v. Pena, 586 F.3d 105, 110 (1st Cir.
6 2009) (citing Daubert, 509 U.S. at 597).

7 “If proffered expert testimony fails to cross Daubert’s threshold for admissibility, a
8 district court may exclude that evidence from consideration when passing upon a motion for
9 summary judgment.” Cortes-Irizarry v. Corporacion Insular de Seguros, 111 F.3d 184, 188 (1st
10 Cir. 1997). The First Circuit, however, has warned that “the Daubert regime should be
11 employed only with great care and circumspection at the summary judgment stage.” Id.

12 The proponent of the expert testimony at issue carries the burden of establishing that the
13 “pertinent admissibility requirements are met by a preponderance of the evidence.” Fed. R.
14 Evid. 702 advisory committee’s note; see also Fed. R. Evid. 104(a). But at this stage, a
15 proponent of evidence need not demonstrate that the expert’s conclusions themselves are
16 correct; Daubert merely requires a showing that “the expert’s conclusion has been arrived at
17 in a scientifically sound and methodologically reliable fashion.” Ruiz-Troche v. Pepsi Cola of
18 P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998).

19 In Daubert, the Supreme Court “outlined a flexible, non-exclusive set of criteria
20 for admitting expert testimony,” including “(1) whether a theory or technique can be (and has
21 been) tested; (2) whether the theory or technique has been subjected to peer review and
22 publication; (3) the known or potential rate of error; (4) and general acceptance in the relevant

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1 scientific community.” Granfield v. CSX Transp., Inc., 597 F.3d 474, 485–86 (1st Cir. 2010)
2 (internal quotation marks omitted) (citing Daubert, 509 U.S. at 593–94.). The overarching
3 concern in the admissibility assessment of “proposed expert testimony ‘is the scientific validity
4 -- and thus the evidentiary relevance and reliability -- of the principles that underlie a proposed
5 submission.’” Cruz-Vazquez v. Mennonite Gen. Hosp., 613 F.3d 54, 59 (1st Cir. P.R. 2010)
6 (quoting Daubert, 509 U.S. at 594-95.). We remind the parties that, as the Supreme Court has
7 stated, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction
8 on the burden of proof are the traditional and appropriate means of attacking shaky but
9 admissible evidence.” Daubert, 509 U.S. at 596.

10 II.

11 Discussion

12 Defendant has filed motions to exclude plaintiff expert witness testimony regarding the
13 use of Prempro for nineteen months and increased breast cancer risk, as well as motions to
14 exclude the testimony of various expert witnesses. We discuss each motion below in turn.

15 A. Defendant’s Motion to Preclude Any Expert Testimony that Prempro Use 16 Increases Breast Cancer Risk When Taken for Only Nineteen Months

17 Defendant filed its Motion to Preclude Any Expert Testimony that Prempro Use
18 Increases Breast Cancer Risk When Taken for Only Nineteen Months on October 29, 2010.
19 (Docket No. 57.) Responses, replies, and supplements followed, and oral arguments on the
20 issue were heard on November 29, 2010. For the reasons detailed below, we deny the
21 Defendant’s motion.

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1 Defendant argues that the Women’s Health Initiative (“WHI”) clinical trial conducted
2 by the National Institutes of Health, a randomized clinical trial (“RCT”), provides the “gold
3 standard” among studies of hormone replacement therapy (“HRT”) dangers, and showed no
4 indication of an increased risk of breast cancer within the first five years of Prempro use for
5 HRT. (Docket No. 57-1 at 5–6.) Defendant also points out that Plaintiffs’ causation experts,
6 Dr. Donald Austin and Dr. Graham Colditz, have both made prior statements implying that
7 short-term HRT would not increase breast cancer risks. (Id. at 9.) Finally, Defendant argues
8 that neither Dr. Austin nor Dr. Colditz has reconciled their potentially-contradictory statements
9 with their positions in the current case. (Id. at 10.)¹

10 RCTs such as the WHI study are considered the “gold standard for determining the
11 relationship of an agent to a disease or health outcome.” David H. Kaye & David A. Freedman,
12 Reference Guide on Statistics, in Federal Judicial Center, Reference Manual on Scientific
13 Evidence 338 (2d ed. 2000); see also id. at 338 (noting that “inferences based on well-executed
14 randomized experiments are more secure than inferences based on observational studies”).
15 Defendant argues that the opinions proffered by Plaintiffs’ experts—that Prempro use for
16 nineteen months can increase risk of breast cancer—flies in the face of the WHI study findings,
17 which found no increased risk during such a short time period. (Docket No. 57-1 at 5–6.)

¹In responses to the potentially conflicting statements of Plaintiffs’ experts highlighted by Defendant, Plaintiffs point to other statements made by Dr. Austin and Dr. Colditz, consistent with the proposition that short-term HRT can increase the risk of breast cancer. (Docket No. 130 at 19–21.)

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1 It is beyond dispute that an expert witness cannot give testimony that is not “predicated
2 on facts legally sufficient to provide a basis for the expert’s opinion.” Damon v. Sun Co. Inc.,
3 87 F.3d 1467, 1474 (1st Cir. 1996) (internal citations omitted). In the present case, however,
4 Plaintiffs’ experts do point to different studies to support their conclusions, and we simply
5 cannot find an “analytical gap between the data and the opinion proffered” great enough to
6 render this testimony inadmissible. Joiner, 522 U.S. at 146. Even though the studies relied
7 upon by Plaintiffs’ experts might not carry the same force as the WHI, Defendant has not
8 shown—on this record before us in this case, at this point in time—that such studies fail to
9 provide a sufficient factual basis for the Plaintiffs’ experts’ conclusions.² Ruiz-Troche, 161
10 F.3d at 85.

11 Indeed, it is exactly such conflicting expert testimony that should be “tested by the
12 adversary process—competing expert testimony and active cross-examination—rather than
13 excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily
14 weigh its inadequacies.” Id. (internal citations omitted); see also Granfield v. CSX Transp.,
15 Inc., 597 F.3d 474, 487 (1st Cir. 2010) (internal citations omitted) (finding that disputes over
16 an expert’s “use of differential etiology as a methodology, or lack of textual authority for his
17 opinion, go to the weight, not the admissibility, of his testimony.”)

² This court is unwilling to overstep the bounds of its role as gatekeeper, especially at this late stage in the proceedings. See In re Neurontin Mktg. & Sales Practices Litig., 2010 U.S. Dist. LEXIS 12737, at *52 (D. Mass. Feb. 12, 2010) (denying complex motions filed one month before trial opposing expert testimony as too late to permit sufficient supplemental filings and responses but finding that, at trial, all experts must give “appropriate weight to all available [randomized clinical trials]” before offering opinions on efficacy of a drug).

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1 As for the allegations of prior inconsistent statements made by Plaintiffs' experts
2 regarding the dangers of short-term HRT, any potential inconsistencies in Plaintiffs' experts'
3 testimony go to the weight and credibility of their testimony, and not its admissibility.
4 Rivera-Cruz v. Latimer, Biaggi, Rachid & Godreau, LLP, 2008 U.S. Dist. LEXIS 46562, at *18
5 (D.P.R. June 16, 2008); CTC Commc'ns Corp. v. Bell Atl. Corp., 77 F. Supp. 2d 124, 143
6 (D. Me. 1998).

7 **B. Defendant's Motion to Exclude the Testimony of Michael T. Maloney, Ph.d**

8 We hereby grant in part Defendant's Motion to Exclude the Testimony of Michael T.
9 Maloney, Ph.d., as to any proposed testimony regarding punitive damages. (Docket No. 50;
10 122.) Although we find it problematic that Plaintiffs have not yet had the opportunity to file a
11 written response—as Defendant waited until November 15, 2010, to submit a Memorandum of
12 Law to provide the reasoning behind the motion—we agree with Defendant that any testimony
13 of Dr. Maloney relating to the appropriate amount of punitive damages should be excluded.
14 Damages are compensatory under Puerto Rico law, which does not recognize punitive damages.
15 Noble v. Corporacion Insular de Seguros, 738 F.2d 51, 54 (1st Cir. 1984); In re Caribbean
16 Petroleum, LP, 561 F. Supp. 2d 194, 199 (D.P.R. 2008).

17 **C. Defendant's Motion to Exclude the Testimony of Dr. Suzanne Parisian and**
18 **Dr. Donald Austin**

19 We hold that neither Dr. Parisian nor Dr. Austin should be permitted to testify as to an
20 alleged standard of care in the industry as for testing of pharmaceutical products. (Docket

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1 No. 52-1.) We note that Plaintiffs, in their response, have already averred that Dr. Austin will
2 not testify as to an industry standard of care or any possible breaches by Defendant. (Docket
3 No. 124 at 3.) We also will not hear any testimony from Dr. Parisian regarding punitive
4 damages, which are not recognized under Puerto Rico law. Noble, 738 F.2d at 54.

5 At this stage of the litigation, however, we are unwilling to exclude any other potentially-
6 relevant and helpful testimony from either expert unrelated to a breach of standard of care (for
7 example, testimony as to other testing measures would have been available at the time). In re:
8 Prempro Products Liability Litigation, Civil No. 3:05CV00078 (E.D. Ark., Sept. 16, 2010)
9 (granting Defendant Wyeth's motion to exclude testimony of Dr. Austin and Dr. Parisian on
10 standard of care and what tests a reasonable pharmaceutical company would have conducted).

11 **D. Defendant's Motion to Strike Any Specific Causation Opinions by Dr. Michaels**

12 We grant Defendant's "Motion to Strike Any Specific Causation Opinions by
13 Dr. Michaels," and we will exclude any testimony of Dr. Michaels at trial regarding the
14 particular issue of specific causation. (Docket No. 53-1; 143.) On November 15, 2010,
15 Plaintiffs, in response to Defendant's motion to exclude the causation testimony of
16 Dr. Michaels, unequivocally stated that "Plaintiff does not seek to elicit causation testimony
17 from Dr. Michaels." (Docket No. 120 at 1.) We note that Plaintiffs are free to present
18 Dr. Michaels' pathology analysis as originally planned, but we cannot permit Plaintiffs to
19 present new causation testimony by Dr. Michaels at the eleventh hour—more than three months
20 past the Plaintiff's disclosure of expert testimony and two weeks after making written

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1 declarations to this court that they would not use him to present such testimony. By excluding
2 such testimony we not only protect Defendant from unfair prejudice that would result from
3 unexpected additions to expert testimony at this late stage, but we also protect Rule 26 of the
4 Federal Rules of Civil Procedure from being undermined “by evasion or by dilatory tactics.”
5 Thibeault v. Square D Co., 960 F.2d 239, 244 (1st Cir. 1992); see also Macaulay v. Anas, 321
6 F.3d 45, 51 (1st Cir. 2003) (discussing factors involved in trial court’s response to untimely or
7 changed expert testimony such as the “history of the litigation, the proponent’s need for the
8 challenged evidence, the justification (if any) for the late disclosure,” as well as surprise and
9 prejudice).

10 **E. Defendant’s Motion to Exclude the Testimony of Dr. Michael Wertheimer**

11 We deny Defendant’s Motion to Exclude the Testimony of Dr. Michael Wertheimer.
12 (Docket Nos. 54; 136.) We reject Defendant’s challenges to Dr. Wertheimer’s qualifications.
13 The First Circuit has recognized that a qualification as an expert witness does not require a
14 physician to “be a specialist in a particular medical discipline to render expert testimony relating
15 to that discipline.” Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion Familiar,
16 345 F.3d 15, 24–25 (1st Cir. 2003) (approving general practitioner expert testimony regarding
17 ectopic pregnancies). When evaluating Dr. Wertheimer as a proposed expert, the trial judge
18 must focus on whether the “scientific, technical, or other specialized knowledge he offers will
19 assist the trier better to understand a fact in issue.” Id. at 24 (internal citation omitted).

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1 Defendant will be able to challenge the weight and credibility of his testimony during voir dire
2 and cross-examination.

3 We also reject Defendant's attack on Dr. Wertheimer's use of differential diagnosis.
4 While the First Circuit has affirmed that "a differential diagnosis is a proper scientific technique
5 for medical doctor expert testimony," Granfield v. CSX Transp., Inc., 597 F.3d 474, 486 (1st
6 Cir. 2010), Defendant argues that Dr. Wertheimer's performance of differential diagnosis is
7 unreliable. Specifically, Defendant argues that Dr. Wertheimer has failed to rule out
8 completely other risk factors involved in the causation of breast cancer. Dr. Wertheimer's
9 report does, however, discuss and reject over eleven different breast cancer risk factors.
10 (Docket No. 54-10 at 14–15.) In a similar case involving Prempro, the Eight Circuit upheld the
11 admissibility of similar expert causation testimony derived from differential diagnosis, finding
12 that, like Dr. Wertheimer, the expert witness had satisfactorily "established that hormones were
13 necessary to the development of [Plaintiff's] tumors and conducted her differential diagnosis
14 from this starting point." Scroggin v. Wyeth (In re Prempro Prods. Liab. Litig.), 586 F.3d 547,
15 566 (8th Cir. 2009). We find that Dr. Wertheimer's testimony passes muster for Daubert
16 purposes. Attacks on how thoroughly Dr. Wertheimer ruled out other risk factors go to the
17 weight and credibility—not the admissibility—of his testimony. Id.

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V.

Conclusion

For the foregoing reasons, we hereby **DENY** Defendant's "Motion to Preclude Any Expert Testimony that Prempro Use Increases Breast Cancer Risk When Taken for Only Nineteen Months." (Docket No. 57.) We **GRANT IN PART** Defendant's "Motion to Exclude the Testimony of Michael T. Maloney, Ph.d.," (Docket Nos. 50; 122), as to any proposed testimony regarding punitive damages. We **GRANT IN PART** Defendant's "Motion to Exclude the Testimony of Dr. Suzanne Parisian and Dr. Donald Austin," (Docket No. 52), as to exclusion of testimony regarding an alleged standard of care for testing HRT products. We **DENY** Defendant's earlier motion to "Exclude the Testimony of Dr. Paul Michaels" as **MOOT**. (Docket No. 53.) We **GRANT** Defendant's "Motion to Strike Any Specific Causation Opinions by Dr. Michaels." (Docket No. 143.) We **DENY** Defendant's Motion to Exclude the Testimony of Dr. Michael Wertheimer. (Docket Nos. 54; 136.)

IT IS SO ORDERED.San Juan, Puerto Rico, this 3rd day of December, 2010.

s/José Antonio Fusté
JOSE ANTONIO FUSTE
Chief U.S. District Judge